2013-1662

In The

United States Court of Appeals

For The Federal Circuit

ENDO PHARMACEUTICALS INC.,

Plaintiff – Appellant,

v.

ROXANE LABORATORIES, INC.,

Defendant – Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK IN CASE NO. 13-CV-3288, SENIOR JUDGE THOMAS P. GRIESA.

REVISED NON-CONFIDENTIAL BRIEF OF APPELLEE

Alan B. Clement
LOCKE LORD LLP
3 World Financial Center
New York, New York 10281
(212) 415-8600

Keith D. Parr
Hugh S. Balsam
Myoka Kim Goodin
LOCKE LORD LLP
111 South Wacker Drive
Chicago, Illinois 60622
(312) 443-0700

Counsel for Appellee

Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ENDO PHARMACEUTICALS INC. v. ROXANE LABORATORIES, INC.

No. 2013-1662

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Roxane Laboratories, Inc. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Roxane Laboratories, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Roxane Laboratories, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Boehringer Ingelheim Corporation

4. ☑ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Locke Lord LLP - Alan B. Clement, Keith D. Parr, Scott B. Feder, Hugh S. Balsam, Myoka Kim Goodin, Amanda K. Kelly, Wasim K. Bleibel

September 24, 2013
Date

Signature of counsel

Hugh S. Balsam
Printed name of counsel

Please Note: All questions must be answered
cc: all counsel of record by ECF filing

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Material has been redacted from page 8 of this Principal Brief for Defendant-Appellee Roxane Laboratories, Inc. This material is deemed confidential business information within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure. The material omitted from this page contains Roxane's confidential financial and business information.

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STATEMENT OF RELATED CASES

Under Local Rule 47.5:

(a) Another appeal from the same district court decision is currently pending in this Court—No. 13-1658, which is Endo's appeal against another defendant (Actavis) stemming from the same underlying order. Endo has moved to consolidate the two appeals.

(b) Roxane is unaware of any other case pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF THE ISSUES

1. Was it within the district court's discretion to deny Endo's motion for preliminary injunction based on legal estoppel where:

(a) in settling a prior lawsuit, Endo in 2011 granted Roxane a license and covenant not to sue that allowed Roxane to market its ANDA product;

(b) Endo in this lawsuit seeks to derogate from that 2011 license by asserting three newly acquired patents against Roxane's marketing of its same product involved in the license; and

(c) long-established case law holds that a licensor is legally estopped from asserting newly acquired patents to derogate from rights granted in a previous license?

2. Did the district court correctly disregard the parties' negotiating history leading up to the 2011 license agreement where the negotiating history:

(a) is inadmissible parol evidence because the license terms are unambiguous;

(b) is irrelevant because legal estoppel applies even where the license itself expressly disclaims application to later-issued patents; and

(c) constitutes inadmissible hearsay in any event.

STATEMENT OF THE CASE

This is the second lawsuit Endo Pharmaceuticals Inc. has filed against Roxane Laboratories, Inc. based on the same Roxane generic extended-release oxymorphone product. In the first suit, under the Hatch-Waxman Act, Endo alleged that Roxane's ANDA product, if and when approved and sold, would infringe three specific Endo patents. The parties settled that lawsuit in 2011, with Endo granting Roxane a license and covenant not to sue that would allow Roxane to market its generic product.

Now, despite that earlier license and covenant not to sue, and even though Endo itself has abandoned this particular product, Endo has filed this suit alleging that the same Roxane ANDA product involved in the first suit, if and when sold, would infringe three new patents that Endo obtained in 2012, after the first lawsuit was resolved.

This is Endo's interlocutory appeal from the district judge's denial of Endo's motion for a preliminary injunction to bar Roxane from selling a generic version of a product that Endo has itself abandoned. The judge found that under the timeless principles discussed recently in cases like *TransCore*, *LP v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009), Endo is estopped from derogating from the rights it gave Roxane, in exchange for good consideration, in the 2011 license. Accordingly, Endo may not assert its latest patents against the same licensed Roxane product in this lawsuit.

STATEMENT OF FACTS

Endo grants Roxane royalty-free license with respect to the three originally listed patents.

Endo has marketed extended-release oxymorphone products under the trade name OPANA® ER since 2006. (JA00776-77). Endo's original commercial Opana ER product was a non-crush-resistant formulation. (*Id*.; JA03276-77). Endo listed three patents in FDA's Orange Book that purported to cover that original product: U.S. Patent Nos. 5,662,933 ("the '933 patent"), 5,958,456 ("the '456 patent"), and 7,276,250 ("the '250 patent"). (JA04554).

Years before this lawsuit, Endo sued several generic-drug manufacturers for filing ANDAs seeking FDA permission to sell their own generic versions of Endo's original Opana ER formulation. (JA00781-82). One such manufacturer was Roxane, which filed its ANDA No. 200822 in 2009. (JA00782; JA04661).

Endo promptly sued Roxane under the Hatch-Waxman Act contending that Roxane's proposed product, if and when approved and sold, would infringe the '456 patent. (JA04858-59.) When Roxane counterclaimed for invalidity and non-infringement of the other two Orange Book patents (the '933 and '250 patents, now owned by Endo), Penwest, which then owned the '933 and '250 patents, gave Roxane a covenant not to sue on those two patents. (JA04557-59).

Since then, Endo settled with all the generic filers regarding the Orange Book patents listed for the original Opana ER formulation. (JA00782). Roxane and Endo settled their Hatch-Waxman litigation in March 2011. (JA04561-76). In connection with the settlement, the parties executed a "Settlement and License Agreement." (*Id*.).

Settlement agreement allows Roxane to market its ANDA product.

The 2011 settlement agreement gave Roxane, in exchange for valuable consideration, the right to market its ANDA product free of hindrance from Endo. The agreement granted Roxane:

> a non-exclusive, non-transferable…and royalty-free license…under the Licensed Patents, during the License Term, to make, use, have made, sell, offer to sell, import and use [Roxane's ANDA product] solely in the Territory.

(JA04568).

The "License Term" extends "until the expiration or abandonment of all claims of the Licensed Patents." (JA04569). And the agreement defined "Licensed Patents" as the '933, '456, and '250 patents as well as patents that have a priority relationship with those patents:

> *any* United States patent applications that *claim priority to* the ['933, '456, or '250 patents], *including* any continuation, continuation-in-part and divisional patent applications that claim priority to [the three patents]…in each case that Endo and/or Penwest could assert would be infringed by the making, using, selling, offering to sell or importing of the Roxane Product.

(JA04563, § 1.16(b)) (emphasis added).

In the 2011 agreement, Endo also covenanted not to sue Roxane for infringement of the licensed patents, as follows:

> During the License Term each of Endo and Penwest…covenant that they will not sue, assert any claim or counterclaim against, or otherwise participate in any action or proceeding against Roxane…or any of Roxane's suppliers, distributors, wholesalers or customers… claiming or otherwise asserting that the manufacture, use, sale, offer for sale or distribution of Roxane Products under the Roxane ANDA in the Territory on or after the applicable Commencement Date…by Roxane, infringes the Licensed Patents, so long as Roxane is in compliance with the terms of this Agreement.

(JA04568).

Endo markets its original-formulation Opana ER, but later discontinues it in favor of a crush-resistant formula.

Endo marketed its original-formulation Opana ER from 2006 to 2012, with total sales amounting to more than a billion dollars. (*See* JA00777-78).

Nevertheless, around the time of the Roxane settlement, and unbeknownst to Roxane, Endo was seeking FDA approval of a new NDA for a new extended-release oxymorphone formulation that, as compared to the original formulation, was allegedly crush resistant to deter abuse. (JA00252; JA00779).

FDA did not agree with Endo that the new formulation is crush-resistant to deter abuse. (JA03280-82; JA00780-81). FDA approved the new Endo formulation in late 2011 anyhow, under a separate NDA number. (JA00779; JA03276). But instead of selling both the original and the new formulations of Opana ER, Endo abandoned the original formulation and by June 2012 announced that FDA had moved the original-formulation Opana ER to the Orange Book's discontinued list. (JA00779-80; JA03276). Since early 2012, Endo has been selling only the new formulation, although under the same trade name Opana ER. (JA00779-80; JA03277).

Roxane's product that is the subject of the current lawsuit, on the other hand, remains unchanged from the first lawsuit.

Endo tries to get FDA to refuse to approve any ANDA for generic original-formulation extended-release oxymorphone.

Once Endo ceased selling its original-formulation product, it initiated a series of actions designed to prevent anyone else from selling a generic counterpart to the abandoned original formulation.

In August 2012, Endo filed a Citizen Petition asking FDA to determine that the original, non-crush-resistant formulation of Opana ER—yes, the product Endo had sold more than a billion dollars' worth of—is unsafe. (JA03276; JA00777-78). Endo also asked FDA to refuse to approve any ANDA seeking permission to sell a generic counterpart to the original-formulation product and to withdraw the approval of any ANDA that the agency had already granted. (*Id*.).

FDA denied the petition in May 2013. (JA03276-85). Endo says it is still trying to convince the agency to declare the original formulation unsafe and to disapprove any ANDAs for it—all out of a concern for public safety, or so we are told. (JA00781).

Endo obtains new patents; seeks to prevent Roxane from marketing its generic bioequivalent of the abandoned original-formulation Opana ER.

In addition to pursuing actions at the FDA to prevent competition, Endo has also used the courts to try to squelch generic entry. In late 2012, Endo obtained two new patents (U.S. Patent Nos. 8,309,122 and 8,329,216 ("the '122 patent" and "the '216 patent," respectively)), which share priority with the previously litigated and licensed '250 patent, and bought a third (U.S. Patent No. 7,851,482 ("the '482 patent)), and listed all three in the Orange Book as covering its new formulation of Opana ER. (JA00003; JA00018; JA00047; JA00254). Endo then filed this second lawsuit against Roxane alleging that Roxane's proposed ANDA No. 200822 product—the same ANDA product involved in the earlier lawsuit and the 2011

settlement and license—will infringe these new patents. (JA00250-62). These patents are:

'482 patent

The '482 patent covers oxymorphone hydrochloride with a low amount of a ketone impurity. (JA00003; JA00005, 1:44-46). Endo bought the '482 patent from Johnson Matthey, a supplier of active pharmaceutical ingredients. (JA04597; JA04600; JA04623). As Endo knows, [redacted] Based on this license, Endo has admitted that the '482 patent is not at issue in its appeal against Roxane. (Endo Br. 10).

'122 patent

The '122 patent broadly covers a product long known in the pharmaceutical industry—controlled-release pharmaceutical compositions comprising oxymorphone with a 12-hour dosing interval. (JA00018; JA00033, 2:25-34). In its preliminary-injunction papers, Endo asserted five claims of the '122 patent, claims 1, 2, 3, 16, and 18, each of which defines a controlled-release oxymorphone composition with a specified dissolution profile. (JA01313-15; JA00045-46).

During the '122 patent prosecution, the Examiner repeatedly rejected the claims at issue over the WO 01/08661 publication ("WO '661 publication"). *See In re Huai-Hung Kao*, 639 F.3d 1057, 1062 (Fed. Cir. 2011). After the Board of Patent Appeals and Interferences ("the Board") upheld the Examiner's rejection of claim 1, Endo appealed the decision to this Court, which agreed with the Board that the WO '661 publication taught controlled-release opioid formulations and identified oxymorphone as a preferred opioid. *Id*. at 1066. This Court found that the only aspect of the rejection that needed shoring up was the Board's finding that the claimed dissolution test (USP Paddle Method) could be correlated with the dissolution test (USP Basket Method) used in the prior-art publication that the Examiner cited. *Id.* at 1067. On remand, the Board allowed the claims on the belief that Examiner had not presented sufficient prior art to correlate the USP Paddle Method rates recited in the claims with the USP Basket Method rates disclosed in the WO '661 publication to sustain the rejection. *Ex Parte Huai-Hung Kao*, No. 2009-013710, 2012 WL 3307358, at *4 (B.P.A.I. Aug. 9, 2012).

But neither this Court nor the Board on remand considered two prior-art references that Roxane will assert in this suit: U.S. Patent No. 5,958,452, which teaches sustained-release dosage forms for opioid analgesics including oxymorphone with the claimed dissolution profiles "assessed by USP Paddle or Basket Method" (JA04038; JA04061, 6:23-25; JA04062, 7:35-39; JA04064,

11:60-12:12) or the *Handbook of Dissolution Testing*, which teaches that a stirring rate of 50 rpm for the paddle method is roughly equivalent to 100 rpm for the basket method. (JA04402; JA04404). These references plug the sole evidentiary gap the Court and the Board thought missing from the Examiner's obviousness rejection of the claims.

'216 patent

The '216 patent contains certain claims directed to inherent pharmacokinetic results of extended-release oxymorphone tablets. (JA00047; JA00074-78). Endo's brief misleadingly characterizes one of the '216 patent claims, claim 1, as a "representative claim." (Endo Br. 8-9). But Endo's preliminary-injunction papers against Roxane did not assert claim 1—or any other claim with pharmacokinetic limitations. (JA00547; JA01313; JA01315-18). Instead, Endo asserted only claims 21 and 22 of the '216 patent, which claim pharmaceutical tablets that are prepared by mixing oxymorphone with controlled-release excipients where the tablet has the same dissolution characteristics as those claimed in the asserted claims of the '122 patent. (JA01313; JA01315-18). As such, in an invalidity analysis, the same prior art applies to these claims as applies to the claims of the '122 patent.

Endo moves for preliminary injunction;
court and parties agree to address license issues first.

On July 15, 2013, Roxane received FDA approval of its generic controlled-release oxymorphone product (corresponding to Endo's original formulation). (JA04755). Roxane has agreed to give Endo 30 days' notice of any product launch. (JA04687-89). As of the filing of this brief, that notice has not been given.

Nevertheless, on August 6, 2013, Endo moved for a preliminary injunction against Roxane. (JA00523-24.) In the same motion, Endo sought a preliminary injunction against Actavis to prevent it from selling its own generic counterpart to the original-formulation Opana ER. (Endo Br. 4).

At an initial status conference on August 26, 2013, the defendants (Roxane and Actavis) informed the district judge that there are a variety of reasons why Endo would not be able to sustain its burden to prove that it is entitled to preliminary injunctive relief, not the least of which are the licenses that Endo previously gave the defendants to settle Endo's prior lawsuits against the same accused ANDA products at issue in these lawsuits. (JA06373-75). The judge and the parties agreed that, in the interest of judicial economy, the parties would address the license-related issues first, for if the court found that the licenses alone precluded an injunction, there would be no need to reach the other reasons (patent

invalidity, lack of irreparable harm) that likewise required denial of the preliminary injunction. (JA06388-90).

Thus, Roxane submitted an opposition brief confined solely to the pivotal license-related issues, reserving its right to brief the additional issues if and when appropriate. (JA04806-07; JA04823). Endo, which had not addressed the license issue in its opening preliminary-injunction briefing, then filed its reply brief, also confined to the license issues. (JA04828-29).

At hearing, judge denies preliminary injunction based on this Court's decision in *TransCore*.

At a September 12, 2013 hearing, the district judge determined that the equitable principles discussed recently in *TransCore*, *LP v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009), compelled denial of the preliminary injunction. (JA06439). That case, and the venerable doctrine on which it relies, applies when a patentee has licensed a right, received consideration for the license, but then seeks to derogate from that right by asserting after-acquired patents against the licensee. In that instance, long-established equitable principles preclude a patentee from asserting the new patents to detract from rights previously given—regardless of any contrary wording in the license.

Here the district court cogently determined that Endo had given licenses to the defendants that allowed them to market their generic oxymorphone products; that Endo had received consideration for those licenses; and that Endo was now

seeking to derogate from the marketing right by asserting new patents that would punish the defendants for doing just what the licenses allow. (JA06438-39). As the judge said to Endo:

> You make these agreements. These agreements are acted on. And then you file a couple of new patents, and you say all these things you agreed to let them do infringe the new patents.

(JA06411).

The court concluded that it would be "highly unfair and unjust" if Endo could assert the new patents to stop the activity that the previous licenses allowed. Thus the court ruled:

> I am holding as a matter of law and I'm finding that Endo is estopped from claiming that the activity of Actavis and Roxane, which has gone on for a substantial period of time, is now suddenly barred because of these new patents. For those reasons, the motion for a preliminary injunction is denied.

(JA06439).

This appeal followed.

SUMMARY OF THE ARGUMENT

I. It was well within the district court's discretion to deny Endo's request for preliminary injunction based on legal estoppel. On-point case law from this Court holds that a patentee cannot grant a license that allows another to market its product and then turn around and assert later-issued patents against the licensee to effectively sap the earlier license of its value. This case law is grounded in

ancient principles of equity holding that one cannot sell a right for valuable consideration and then to take action to try to deprive the recipient of the benefit of its earlier bargain.

As the district judge cogently recognized, that is precisely what Endo is trying to do in this lawsuit. In 2011, in settlement of a prior lawsuit, Endo granted Roxane a license that permits it to market its generic controlled-release oxymorphone product corresponding to Endo's original-formulation Opana ER. In this suit, Endo is asserting later-obtained patents against Roxane to deprive Roxane of the benefit of the earlier license. In these circumstances, Endo is legally estopped from asserting the later-issued patents against Roxane.

The estoppel principle is so powerful that it overrides provisions inserted into the earlier license purporting to disclaim any rights in future patents. Thus, legal estoppel applies here despite a "No Implied Rights" clause inserted into the 2011 license.

II. Endo's extensive discussion of the negotiations leading up to the 2011 license is legally irrelevant. First, it is 100% parol evidence, which is inadmissible to vary the terms of an unambiguous agreement. The court did not find the license agreement ambiguous, so the negotiations are inadmissible. Second, estoppel overpowers even express provisions in a license purporting to limit rights in later-issued patents—which is the strongest possible statement of the parties' intent,

certainly stronger than statements made during negotiations. And third, the conversations recounted in Endo's negotiation history are pure hearsay and inadmissible for that reason as well.

ARGUMENT

Introduction/Legal Standards

Endo presented the district judge with a disjointed, evasive, and legally unsupportable argument and now Endo criticizes the judge for not accepting it. The criticism is unmerited, as are Endo's *ad hominem* attacks. Many of Endo's attacks are not even directed at the judge's basis for ruling against Endo. Instead, they are leveled at the judge's questioning of Endo's counsel during oral argument or the judge's comments in connection with the issue of express license, a ground the judge ultimately did not need to reach because he found against Endo on the basis of estoppel.

Endo's criticism of the district judge is undeserved regardless. For instance, the judge did not "candidly admi[t] that he was sitting 'almost as a layman,'" as Endo uncharitably suggests. (Endo Br. 17). Rather, the judge's point was that even a layman would see the unfairness in Endo's granting Roxane a license enabling Roxane to sell its product only to obtain new patents to assert against Roxane to try to sap the license of its value. (JA06411).

Likewise, the judge did not base his ruling on the implication "that entering into a patent license and then suing on later-issued patents was somehow un-American." (Endo Br. 22). Rather, the judge followed on-point precedent holding that one cannot grant a license and then turn around and gut the value of the license by suing on later-issued patents regardless of what the license says.

Nor was the judge's view of estoppel "over-simplistic," as Endo also adverts. (Endo Br. 22). It is the concept of estoppel in the first instance that is simple, rooted as it is in basic notions of fairness, a concept the experienced judge readily and appropriately grasped, and then concisely explained in his ruling from the bench:

> What is clear, however, to me is this. That an agreement was made, and whether it is called a license agreement or an agreement not to sue I won't worry about for the moment. We'll call it a license agreement because that's how things have been described by the lawyers today. We're talking about licenses.
>
> And what is clear is that those licenses, or that license, gave permission to Actavis and Roxane to go forward with marketing the products and seeking permission for the marketing of the products that have been the subject of their activity since the time of the litigation up to and including the present moment.
>
> There is a doctrine bearing the name estoppel, and there's case law about the problem we have here. And that is where a license is given, or permission is given, or where for any other reason it is legal for a company to market a product and such marketing is done and then another company comes in with new patents and says you infringe my new patents, under the circumstances that we have here, which may be different from other circumstances, but under the circumstances that we have here that is a highly unfair and unjust situation if that

> were to be—if infringement of the new patents would stop the marketing and permitting process that was going on by Actavis and Roxane.
>
> Consequently, I am holding as a matter of law and I'm finding that Endo is estopped from claiming that the activity of Actavis and Roxane, which has gone on for a substantial period of time, is now suddenly barred because of these new patents. For those reasons, the motion for a preliminary injunction is denied.

(JA06438-39).

Thus, in denying the injunction, the district court found that Endo had no chance of prevailing on the merits because Endo is not permitted to derogate from the rights it gave Roxane in the 2011 license agreement.

As Endo agrees, this Court reviews only for an abuse of discretion the district court's decision to deny a preliminary injunction. *Gen. Protecht Grp.*, *Inc. v. Leviton Mfg. Co.*, 651 F.3d 1355, 1359 (Fed. Cir. 2011). Further, there is another level of deference at play here because findings with respect to estoppel are likewise firmly within the district court's discretion. *See Ecolab*, *Inc. v. Envirochem*, *Inc.*, 264 F.3d 1358, 1364 (Fed. Cir. 2001) ("The standard of review for both laches and equitable estoppel is abuse of discretion."); *Scholle Corp. v. Blackhawk Molding Co.*, *Inc*., 133 F.3d 1469, 1471 (Fed. Cir. 1998) ("The district court's finding of equitable estoppel is then reviewed under an abuse of discretion standard.").

In the district court, the parties agreed to focus initially on only one reason why the injunction should not issue: the 2011 license that Endo gave Roxane (and the concomitant license that Endo gave to Actavis). But there are additional independent reasons why Endo is not entitled to the injunction it seeks, including no likelihood of success on the merits due to patent invalidity and the lack of irreparable harm. The district court did not need to reach these alternate grounds for denying the injunction, but an injunction cannot issue without a court first addressing them. Accordingly, if the Court should disagree with the district court's conclusion with respect to the license, a remand would be necessary for the district court to address all the other grounds that compel denial of the injunction. Endo agrees. (Endo Br. 35).

I. The district court properly exercised its discretion to deny the injunction based on legal estoppel as discussed in *TransCore*.

The district court acted well within its discretion in denying the preliminary injunction and this Court should affirm the ruling. The court found: that Endo gave Roxane a license in 2011 that permitted Roxane to market the product of its ANDA No. 200822; that Endo obtained valuable consideration in exchange for that license; that Roxane proceeded to rely on the license in pressing forward with FDA to obtain approval of its ANDA; and that it would be eminently unfair for Endo to turn around and assert three later-obtained patents against Roxane, thereby eviscerating the benefit of the 2011 license in an effort to preclude Roxane from

doing (marketing its product) precisely what the 2011 license allowed. (JA06438-39). The judge's ruling and reasoning were right on the money.

A. More than a century of precedent compelled the district court's holding on legal estoppel.

The district court based its holding on *TransCore*, *LP v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009), which Roxane and Actavis discussed extensively in their written papers and their oral presentations. In that case, TransCore had previously sued Mark IV for infringement of several patents. *Id.* at 1273. The parties settled, with Mark IV granting valuable consideration in exchange for a covenant not to sue and a release of all of TransCore's existing claims against it. *Id.* A few years later, TransCore accused a Mark IV customer of infringing the three patents that had originally been in suit as well as a new patent that issued after the settlement. *Id.*

This Court held that TransCore was legally estopped from bringing an action against Mark IV's customer because that would derogate from the rights TransCore had expressly granted to Mark IV in the previous settlement. *TransCore*, 563 F.3d at 1279. The estoppel covered not only the patents that existed at the time of the settlement, but also the patent that was not yet in existence—*even though the settlement agreement had expressly stated that it "shall not apply to any other patents … to be issued in the future." Id.* (emphasis added). The Court based its decision on equitable principles: once a licensor

grants a definable property right for valuable consideration, equity does not permit it to detract from that right. *Id.*

Since *TransCore*, this Court has consistently applied these core equitable principles. *See Intel Corp. v. Negotiated Data Solutions*, *Inc.*, 703 F.3d 1360, 1366-67 (Fed. Cir. 2012) (holding that *TransCore* applies to later-issued reissue patent); *Gen. Protecht Grp.*, 651 F.3d at 1361 (holding that covenant not to sue as to two patents created an implied license as to two later patents).

While these are recent decisions, the legal estoppel rule they apply is a mainstay of the common law. Cases dating at least from the nineteenth century hold that a patentee cannot sell his rights to another via a license as Endo did, buy or obtain control of another patent, and through that later-obtained patent dispossess the assignee of the full benefit of what he purchased. *See Curran v. Burdsall*, 20 F. 835, 837-38 (N.D. Ill. 1888) (holding that where a patentee assigned his rights to the defendant and then, after the sale, acquired an earlier-issued patent covering the scope of the purchased patent, "it would be grossly unjust and inequitable to allow [the patentee] to defeat his assignee's rights to the full enjoyment of this patent by acquiring the ownership of this older patent").

Courts, including this Court's predecessor court, have consistently applied the legal-estoppel rule to preclude a licensor from derogating from rights it previously granted. *See AMP, Inc. v. U.S.*, 389 F.2d 448, 454 (Ct. Cl. 1968)

(company that gave government a license that permitted government to practice and to license a certain patent could not derogate from that right by asserting against the government a different, later-acquired patent); *Frederick B. Stevens*, *Inc. v. Steel & Tubes*, *Inc.*, 114 F.2d 815, 819-20 (6th Cir. 1940) (where a patent owner grants a licensee the right to use a patented machine, the grant carries with it, by necessary implication, a license under any other of the licensor's patents that would be infringed by operation under the grant); *Scoville Mfg. Co. v. Radio Corp. of Amer.*, 9 F. Supp. 239, 241 (S.D.N.Y. 1935) (where two related patents were licensed to two different entities, the right to practice the unlicensed patent was deemed necessary lest the transferee be deprived of what he had contracted for).

The principles discussed in these cases apply with full force here. Under the 2011 settlement agreement, Roxane gave Endo valuable consideration in return for a license and covenant not to be sued that gave Roxane the right to enter the market with the product of its ANDA No. 200822. (JA04561-79). In entering the agreement, Roxane sought to eliminate infringement risk and to effectuate peace with Endo. Now Endo is trying to eviscerate the benefit of that earlier settlement by seeking to enjoin Roxane from selling the same product that the 2011 license allowed Roxane to sell. That would deprive Roxane of the benefit of its earlier bargain. Equity—as well as controlling precedent of this Court—does not condone such a result.

Endo's reliance on the "No Implied Rights" provision in the license agreement is misguided. (Endo Br. 26). This Court has already addressed substantively the same argument in *TransCore*, where the license included a similar express provision saying that it does not apply to later-issued patents. This Court stated that while this type of "language may protect TransCore against broad claims that future patents generally are impliedly licensed, …it does not permit TransCore to derogate from the rights it has expressly granted and thus does not preclude a finding of estoppel." *TransCore*, 563 F.3d at 1279. Thus, as shown in *TransCore* and in other cases, the equitable principle of estoppel must override any such provision in the license purporting to limit the licensee's future rights as to the licensed product. The point of these cases is that any such provision cannot be interpreted to derogate from the rights granted in the license, and equity accordingly will overlook such self-serving provisions that the licensor includes. *See Minnesota Min. & Mfg. Co. v. E. I. du Pont de Nemours & Co.*, 448 F.2d 54, 55-58 (7th Cir. 1971) (holding that the "doctrine of estoppel prevents a literal application" of explicit provisions in earlier settlement agreement excluding later-issued patent).

In the face of this unshakeable estoppel authority, all Endo musters are three cases that, Endo says, hold that courts will not imply into contracts terms that conflict with express contract terms. (Endo Br. 28 (*citing Vacuum Concrete Corp.*

of Am. v. Am. Mach. & Foundry Co., 321 F. Supp. 771 (S.D.N.Y. 1971), *Enzo Biochem*, *Inc. v. Johnson & Johnson*, 1992 WL 309613 (S.D.N.Y. Oct. 15, 1992), and *Eastern Electric*, *Inc. v. Seeburg Corp.*, 427 F.2d 23 (2d Cir. 1970))). But these are run-of-the-mill breach-of-contract cases involving parties to joint ventures or royalty agreements being accused of failing to use their best efforts under the agreement, thereby depriving the plaintiff of royalties or other revenue. What is missing in these cases is the critical equitable element of estoppel, which, as *TransCore* shows, applies notwithstanding express contractual terms purporting to limit the licensee's rights.

Endo tries to portray *TransCore* as premised on the fact that the later-asserted patent was a continuation of the first. (Endo Br. 33). But by any fair reading the case does not turn on that point. The Court's discussion of legal estoppel in *TransCore* never mentions limiting the legal estoppel to situations involving "continuation" applications. Rather, the critical fact was that "in order for [the licensee] to obtain the benefit of its bargain with [the licensor], it must be permitted to practice the [later-issued] patent to the same extent it may practice the [covenanted] patents." *TransCore*, 563 F.3d at 1279. Same here.

Likewise, in the older cases that apply estoppel based on a previous license it makes no difference whether or not the later-issued patents are continuations of the earlier licensed patents. *See Curran*, 20 F. at 836 (involving later-acquired

patent unrelated to the originally assigned patent); *Frederick B. Stevens*, *Inc.* 114 F.2d at 819 (involving the grant of a right to use a patented machine); *AMP Inc.*, 389 F.2d at 451 (involving a "dominating" but unrelated patent). What is important is whether, by asserting the later-issued patents, the licensor is trying to deprive the licensee of the rights granted in the license, and that can occur regardless of whether there is a priority relationship between the earlier and the later-asserted patents. Of course here, as explained below, there is such a priority relationship between the earlier licensed '250 patent and the two later '122 and '216 patents that Endo asserts against Roxane in this appeal. But estoppel would apply regardless.

Endo also tries to distinguish *TransCore* and Roxane's other authority on the basis that in those cases the accused product would infringe "both the old and the new patents." (Endo Br. 32). Endo overlooks that we have precisely that here. In its first complaint, Endo alleged that Roxane's ANDA product infringes the "old" '456 patent (JA04858-59), and Endo's latest complaint alleges that the same product infringes the "new" '122 and '216 patents (JA00250, JA00257-60). Thus the commonality that Endo reads into the case law is present here even if there is no alleged infringement of the '250 patent (Endo Br. 33).

B. The district court appropriately determined the scope of the rights granted in the 2011 license.

Endo is on no more solid ground when it criticizes the district court for not sufficiently ascertaining the scope of the rights granted in the 2011 license. (Endo Br. 22-24). The court found, quite correctly, that the 2011 license allowed Roxane to prepare to market (via the ANDA process and otherwise), and then to market, its ANDA product:

> And what is clear is that those licenses, or that license, gave permission to Actavis and Roxane to go forward with marketing the products and seeking permission for the marketing of the products that have been the subject of their activity since the time of the litigation up to and including the present moment.

(JA06438-39).

Under *TransCore* the scope of this finding was completely appropriate. In *TransCore*, this Court stated that "the district court properly concluded that for Mark IV to obtain the benefit of its bargain with TransCore, it must be permitted to practice the '946 patent to the same extent it may practice the '183, '275, and '082 patents." *TransCore*, 563 F.3d at 1279. The same is true here: in order for Roxane to obtain the benefit of its settlement agreement with Endo, Roxane must be permitted to practice the '122 and '216 patents (and the '482 patent) to the same extent it may practice the previously licensed '456, '933, and '250 patents. In fact, it is telling that Endo does not deny—nor can it deny—that the 2011 license gave

Roxane a marketing right and that the present lawsuit asserting later-acquired patents seeks effectively to take that right away.

Endo's argument about scope conflates an express-license analysis with estoppel. Since the district court did not decide the motion based on express rights, it did not need to go any further than it did to interpret the 2011 license.

C. Application of legal estoppel is not unfair to Endo.

There is no merit to Endo's complaint that it is somehow unfair for the court to have granted Roxane, through legal estoppel, rights purportedly beyond those contained in the 2011 license. (Endo Br. 20-21, 31). First and foremost, Roxane is not receiving any rights beyond those contained in the 2011 license. The 2011 license granted Roxane the right to market its ANDA product. That is all the district judge maintained, via legal estoppel, in denying Endo's preliminary injunction, namely, that Roxane could sell its ANDA product. Second, even assuming the district judge gave Roxane rights beyond those in the 2011 license, the doctrine of estoppel by its very nature is extra-contractual, where equity implies an obligation that might not otherwise exist at law. *See generally* 28 AM. JUR. 2D ESTOPPEL AND WAIVER § 1 (2013) (estoppel is based on equity and can preclude a party "from asserting rights that might perhaps have otherwise existed."). Third, the district judge did not invent the concept of legal estoppel. As shown above, the doctrine appears in decisions old and new, including recent case

law (*TransCore* was decided in 2009) of which Endo presumably was aware. And last, Endo ignores that legal estoppel applies here to *prevent* unfairness—unfairness to Roxane, which gave valuable consideration for a right that Endo is now seeking to undermine.

II. The negotiations leading to the 2011 license are irrelevant.

Endo devotes the lion's share of its appeal brief to an exposition and discussion of the parties' negotiations that culminated in the 2011 license agreement, and then criticizes the judge for not giving them credence (although he did consider them, JA06426-27). For several reasons these negotiations are irrelevant to any issue here. First, the license is unambiguous, rendering parol evidence inappropriate, and moreover it grants Roxane an express license (a ground the parties briefed but the district judge did not need to reach). Second, estoppel is so powerful that it overrides even express provisions in a license saying that it is not intended to cover future patents, so estoppel certainly also overrides statements Endo alleges were purportedly made to similar effect during negotiations. And third, the "evidence" of negotiations on which Endo relies is inadmissible hearsay in any event.

A. The license terms are unambiguous and grant an express license to Roxane.

The first reason why Endo's discussion of the parties' 2010-11 negotiations is irrelevant is because the terms of the resulting license agreement are

unambiguous. The district court did not find the 2011 license ambiguous. And under New York law—including the case Endo cites in its appeal brief (Endo Br. 27 n.10)—parol evidence is inadmissible to contradict the terms of an unambiguous agreement. *Picture Patents*, *LLC v. Aeropostale*, *In*c., 788 F. Supp. 2d 127, 138 (S.D.N.Y. 2011) ("if a contract is "clear and unambiguous on its face," court cannot "consider parol evidence to interpret it or search for the parties' intent") (internal citation omitted).

In fact, the unambiguous terms of the license agreement give Roxane an express license in the '482, '122, and '216 patents. (Since Endo does not deny that Roxane has a license in the '482 patent, we will confine this discussion to the '122 and '216 patents.) As stated earlier, the 2011 license defined the term "Licensed Patents" to include:

> any United States patent applications that claim priority to the OPANA® ER Patents, including any continuation, continuation-in-part and divisional patent applications that claim priority to the OPANA® ER Patents…in each case that Endo and/or Penwest could assert would be infringed by the making, using, selling, offering to sell or importing of the Roxane Product.

(JA04563, § 1.16(b)).

The use of the word "including" shows that the license covers more than just "continuation, continuation-in-part and divisional applications that claim priority to the Opana ER patents." It also includes any other patent applications that "claim priority" to the Opana ER patents. And because the Opana ER patents are defined

as the '933, '456, and '250 patents, section 1.16(b) necessarily embraces any patent applications that claim priority to any applications and provisional applications from which the '933, '456, and '250 patents likewise claim priority.

As Endo points out in its brief, the fact that the '122 and '216 patents claim priority to the '250 patent is evident from the patents themselves. Endo admits that the '122 and '216 patents "claim[] priority to U.S. Provisional Patent Application Serial Nos. . . . 60/303,357, filed Jul. 6, 2001 . . ." (Endo Br. 9-10). But as Endo knows from the hearing (JA06394-97; JA06414), the '250 patent, one of the "Licensed Patents," also claims priority to that very same U.S. Provisional Patent Application Serial No. 60/303,357, filed July 6, 2001. The '122 and '216 patents are thus "Licensed Patents" under the 2011 agreement because they claim priority to an application to which the '250 Opana ER patent claims priority.

Endo's effort to manufacture an ambiguity in the 2011 agreement strains credulity because Endo seeks to limit Roxane to continuations, continuations-in-part, and divisionals of the Opana ER patents. That reading cannot be correct because it would read out of section 1.16(b) the word "including" and the term "any United States patent applications that claim priority…" Other than "continuation, continuation-in-part and divisional patent applications," the only other applications that "claim priority to" the Opana ER patents could be those,

such as the '122 and '216 patents, that claim priority to a similar regular or provisional patent application.

Endo not only fails to provide the Court with a complete picture of the priority claim, but also neglects to inform the Court of the reason for the priority claim. As shown to Judge Griesa at the hearing with demonstrative slides, more than just a formal priority binds the '250 patent to the '122 and '216 patents. (JA06416-22). There is an important substantive relationship between the patents as well. The '357 provisional application, to which the '250, '122, and '216 patents all claim priority, is the basis for the dissolution profile claimed in the '122 and '216 patents and exhibited by the sustained-release formulations claimed in the '250 patent. (JA04790-91; JA04767, 9:13-19; JA04767, 10:58-JA04768, 11:12; JA00034, 3:34-40; JA00037, 10:48-64; JA00045, 25:50-67; JA00063, 3:34-40; JA00066, 10:48-64; JA00075, 28:10-27).

For these reasons, the license terms are unambiguous and Endo's extended discussion of the negotiating history should be rejected. In the final analysis, however, the court's holding on estoppel obviated any need to discuss these negotiations, because there is no dispute of the basic facts on which the estoppel was based: Endo licensed Roxane under patents covering Roxane's ANDA product in return for settlement of the first litigation, and Endo obtained later patents that it

seeks to assert against Roxane that would derogate from the right Endo previously granted to Roxane.

B. Estoppel applies even where the express contract language (and not just the purported negotiating history) disclaims any rights in later-issued patents.

There is a second but equally fundamental reason why Endo's reliance on the parties' negotiating history is irrelevant. Estoppel overrides even *express contract language* disclaiming rights under license to later-issued patents. And if estoppel overrides express contract language, *a fortiori* it also overrides the purported expression, during negotiations, of a purported intent to disclaim such application to later-issued patents.

TransCore illustrates this point perfectly. In that case, the license agreement contained an express provision that it "shall not apply to any other patents … to be issued in the future." *TransCore*, 563 F.3d at 1279. Nevertheless, this Court found that the equitable principles compelling application of legal estoppel applied despite that contract language. *Id*.; *see also Minnesota Min.*, 448 F.2d at 56-58 (holding that licensor was estopped from asserting a later-issued patent against the licensee even though the explicit terms of the settlement agreement stated that "No right or license is granted by either party hereto under any claim of any patent … other than those specifically mentioned above in Articles II and III").

If estoppel applies despite the license's express language disclaiming the license's application to future patents, surely it applies despite alleged evidence of *negotiations* for a provision disclaiming the license's application to future patents. The negotiations that Endo relies on are accordingly irrelevant and the district court was right on the mark to disregard them.

C. The negotiations are inadmissible hearsay.

Finally, there is an even more basic reason why the district judge was correct to ignore Endo's discussion of the parties' negotiations, and that is that they are riddled with hearsay. The centerpiece of Endo's argument on the purported intent of the parties is paragraph 39 of the affidavit of Endo's Guy Donatiello, where Donatiello recounts discussions he purportedly had with Roxane's David Dow. (*See* Endo Br. 28, citing JA04867).

These statements are pure, unadulterated hearsay. Endo is trying to introduce out-of-court statements of both Dow and the declarant Donatiello in an effort to prove the truth of the matter asserted—that Roxane knew that Endo was unwilling to forgo its right to sue Roxane on the later-issued patents. Such statements are inadmissible unless an exception applies to the rule against hearsay, and none does here. *See* FED. R. EVID. 801(c) (defining hearsay); FED. R. EVID. 802 (hearsay inadmissible).

Even setting aside the hearsay problems for a moment, it is inaccurate for Endo to spin the negotiations as entirely one-sided with Endo getting all it wanted and giving up nothing. As Endo's papers show, Endo initially tried to give Roxane only a narrow license limited solely to the '456 and the '933 patents. (JA04934). But ultimately, after negotiation, Endo broadened the license to include both the '250 patent and "any application claiming priority to the Licensed Patents, such as but not limited to continuations, continuations in part or divisionals thereof . . ." (JA04966-67). Thus, at the end of the day, the final wording was considerably broader than what Endo initially wanted. If anything, the negotiations support the unambiguous nature of the agreement, that it included applications claiming priority to the Opana ER patents beyond just "continuation, continuation-in-part or divisional patent applications."

The back and forth, inadmissible as it may be, merely highlights the importance of interpreting the final wording as written. Of course, it is not necessary even to do that because the judge acted well within his discretion to deny the injunction based on estoppel.

III. The court did not need to make findings on the other injunction factors once it found as a matter of law that an implied license arose due to legal estoppel.

Endo takes the district judge to task for not making findings on the other injunction factors before denying the injunction. But *TransCore* itself illustrates

that once the court finds that legal estoppel gives rise to an implied license, the patentee should not be able to go forward with its suit. *See TransCore*, 563 F.3d at 1280 (entering judgment as a matter of law for defendant). In that event, not only should the injunction be denied, but judgment should be entered for the defendant.

Here the district judge found as a matter of law that legal estoppel applied. (JA06439). That was more than enough to deny the injunction. The court nevertheless gave Endo the benefit of the doubt and *only* denied the injunction. Endo has no cause to complain.

CONCLUSION

For the above reasons, the district judge acted well within his discretion, and committed no legal error, in denying Endo's motion for preliminary injunction. The order should be affirmed.

Alternatively, the case should be remanded for the district court to consider the other reasons—on which briefing and decision were reserved—why a preliminary injunction should not issue, including obviousness and the lack of irreparable harm.

Respectfully submitted,

ROXANE LABORATORIES, INC.

By: /s/ Alan B. Clement

Alan B. Clement
Locke Lord LLP
3 World Financial Center
New York, New York 10281
(212) 415 8600
(212) 812-8378 Facsimile
aclement@lockelord.com

Keith D. Parr
Hugh S. Balsam
Myoka Kim Goodin
Locke Lord LLP
111 South Wacker Drive
Chicago, Illinois 60622
(312) 443-0700
(312) 896-6271 Facsimile
kparr@lockelord.com
hbalsam@lockelord.com
mkgoodin@lockelord.com

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 27th day of December, 2013, I caused this Revised Non-Confidential Brief of Appellee to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

Martin J. Black
Vincent A. Gallo
Joseph R. Heffern
DECHERT LLP
Circa Centre
2929 Arch Street
Philadelphia, Pennsylvania 19103
(215) 994-4000

Jonathan D.J. Loeb
DECHERT LLP
2440 W. El Camino Real, Suite 700
Mountain View, California 94040
(650) 813-4800

Robert Rhoad
DECHERT LLP
902 Carnegie Center, Suite 500
Princeton, New Jersey 08540
(609) 955-3200

Counsel for Appellant

/s/ Alan B. Clement
Counsel for Appellee

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/s/ Alan B. Clement
Counsel for Appellee